DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 14, 2015

KleenGel, LLC
c/o Ms. Maria Griffin
mdi Consultants, Inc
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K143177
Trade/Device Name: KleenGel Dispenser
Regulation Number: 21 CFR 880.6430
Regulation Name: Liquid Medication Dispenser
Regulatory Class: I
Product Code: KYX, KMJ
Dated: August 10, 2015
Received: August 12, 2015

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143177

Device Name

KleenGel Dispenser

Indications for Use *(Describe)*

The KleenGel hands-free dispenser is used to dispense lubricating gel for use by healthcare providers when performing pelvic and rectal exams and other procedures requiring lubricating gel.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR §807.92.

The assigned 5l0(k) number is: K143177

1. Submitter's Identification:

KleenGel, LLC
136 NW 16th Street
Boca Raton, FL 33432
TEL: (561) 705-0452

Contact Person: Suzanne Mair

Date Summary Prepared: August 7, 2015

2. Trade Name of the Device: KleenGel Dispenser

3. Common or Usual Name: Liquid Medication Dispenser

4. Classification:

Regulation:	21CFR 880.6430, Liquid Medication Dispenser
Product Code:	KYX, Class I, 510(k) exempt
Secondary Product Code:	KMJ

5. Predicate Device Information:

Cyclotech Cyclosporine Oral Solution Dispenser - K980109
Referenced device: HR Lubricating Jelly – Preamendment Device

6. Device Description:

The KleenGel Dispenser is a patented automatic dispenser designed to efficiently and hygienically dispense lubricating gel for use by health care providers when performing pelvic and rectal exams or other procedures requiring the use of lubricating gel.

The KleenGel Dispenser has an Infrared Sensor for automatic dispensing of lubricating gel onto the providers fingers or on a medical instrument. The unit is designed to be placed on a counter top so it's easily accessible to healthcare providers in exam rooms. The device is battery operated, using four (4) AA (1.5V) batteries. Device also has an optional AC adapter.

Sterile Lubricating Gel, (sold separately) is packaged in a 14 oz pre-filled disposable cartridge. Gel is dispensed in 3 volume selections, 1ml, 2ml or 3ml

7. Intended Use:

The KleenGel hands-free dispenser is used to dispense lubricating gel for use by healthcare providers when performing pelvic and rectal exams and other procedures requiring lubricating gel.

8. Technological Comparison to Predicate Devices:

Item	KleenGel Dispenser	Predicate Device: K980109	Referenced Device: HR Lubricating
Intended Use	The KleenGel hands-free dispenser is used to dispense lubricating gel for use by healthcare providers when performing pelvic and rectal exams and other procedures requiring lubricating gel.	The CycloTech Cyclosporine Oral Solution Dispenser is intended to dispense SangCya Cyclosporine Oral Solution USP (for microdispersion) as well as display and store dose size, time to next dose, remaining available doses and doses dispensed.	HR Lubricating Jelly is sterile lubricating gel for use by healthcare providers when performing pelvic and rectal exams and other procedures requiring lubricating gel.
Mechanism of dispensing	IR sensor detection to activate pump	Push button to activate pump	Designed to be used with the KleenGel Dispenser.
Power source	Four (4) AA (1.5V) batteries or AC adapter	Four (4) AA (1.5V) batteries	N/A
Software	Yes	Yes	N/A
Materials	High impact Polystyrene	Molded plastic outer case	N/A

Discussion

The intended uses of the KleenGel dispenser and Cyclotech Cyclosporine Oral Solution Dispenser do not differ. Both are designed to dispense a liquid/gel substance in a predetermined amount when the pump mechanism is activated. The predicate device has additional features, which is reflected in the intended use that do not apply to the subject device.

The Kleengel dispenser is only intended for use in a physician office or hospital and the predicate device is intended to be used at home as well.

Both devices dispense gel/solution from specially designed containers that can only be used

with the specific dispenser. The Kleengel dispenser is activated via a sensor and the Cyclotech Cyclosporine Oral Solution Dispenser is activated when a button is pushed. Each dispenser uses proprietary software. The difference in software and in the activation of the dispensing pump has been successfully validated to assure the specifications have been met.
The Kleengel dispenser also offers an option for use with an AC adapter. The power supply has been tested by a third party lab to assure safety of the device to UL61010-1 3rd edition.
The gel that is dispensed from the Kleengel dispenser is identical to the HR Lubricating Jelly that is a preamendment device.
Based on the information contained within the submission, we conclude that the devices are substantially equivalent.

9. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Bench testing was performed to assess the functionality of the KleenGel dispenser including:

UL61010-1 3rd edition *Safety Requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General Requirements*

FDA's guidance document entitled "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" was used when evaluating the device software. Software Validation Testing was performed to assure that the sensor and measurement features of the dispenser function as intended. The results from the *Volume Dispensing Test Protocol* demonstrated that the proper amounts of gel were dispensed for each setting each time the sensor was activated.

Leachable and Extractable testing were performed according to USP 661 to evaluate the presence of leachable materials in the KleenGel cartridge system. Results show that any pharmaceutical preparation based on an aqueous and/or alcoholic matrix will not pick up any significant contamination when stored in these KleenGel Dispenser Cartridge materials.

10. Discussion of Clinical Tests Performed:

Clinical testing was not performed.

11. Conclusions:

Based on the information provided in this submission we conclude that the KleenGel Dispenser is substantially equivalent to the predicate.